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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,824	01/09/2001	Beverly L. Davidson	875.043US1	8235

21186 7590 12/03/2002

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/03/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,824

Applicant(s)

DAVIDSON ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-48 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-48 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 9/16/02 (paper no. 13) is acknowledged and entered into the record. Accordingly, claims 34 and 38 have been amended, claim 62 is newly added. Therefore, claims 34-48, and 62 are pending and examined on the merits.
2. The declaration of Dr. Davidson is acknowledged and considered in response to the amendment filed 9/16/02 (paper no. 13). It is noted that a substitute declaration, filed 10/16/02 (paper no 15) was submitted to replace a declaration filed 9/16/02 (paper no. 14). However, the substitute declaration is defective due to a missing appendix A to which it refers. In order to provide compact prosecution of the instant application, the appendix A filed with the declaration filed 9/16/02 will be considered.

Claim Objections Withdrawn

3. The objection to claim 38 is withdrawn in view of the amendment to the claims.

Claim Rejections Withdrawn- 35 USC § 112, 2nd paragraph

4. The rejection of claims 34-48 under 35 USC 112, 2nd paragraph as being indefinite in the recitation of the phrase "operatively linked" and of the term "soluble" is withdrawn in view of the amendments and the arguments set forth by the applicant.

Claim Rejections Withdrawn- 35 USC § 112, 1st paragraph

5. The rejection of claims 34-48 under 35 USC 112, 1st paragraph as lacking enablement with respect to operative linkage of protein to nucleic acids is withdrawn in view of the amendments set forth by the applicant.

Claim Rejections Maintained- 35 USC § 112, 1st paragraph

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6. The rejection of claims 34-48 and now newly added claim 62 under 35 USC 112, 1st paragraph as being enabling for a b-gal fused to a PTD sequence but not enabling for all type of proteins fused to PTD is **maintained** for the reasons of record. Applicant argues that the specification has provided enabling disclosure through the performance of proof-of principle experiments, wherein over the skilled artisan could substitute other proteins of interest into the general schema of fusion protein design. Applicant further provides a declaration (herein referred to as Davidson Declaration) to provide additional support for the enablement of the instant invention. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. Firstly, the specification of the instant invention has only provided enough information to fuse a β -galactosidase to the PTD sequence. The fusion of other proteins has not been taught in the form of working examples. One of skill in the art would undergo undue experimentation to practice the invention commensurate in scope to the claims because the construction of fusion proteins is not a simple task. Many factors, such as folding, activity, and functionality are changed upon the manipulation of an amino acid sequence. The addition or deletion of a single amino acid could change the entire conformation of a protein and effects its in vivo activity. As such, the addition of a PTD sequence although functional and effective for β -galactosidase does not reasonable confer the same success to other proteins, such as secreted proteins, nuclear proteins, and cytoplasmic proteins as it related to in vivo activity. Secondly, the Davidson Declaration provides insight into the expression of another lysosomal enzyme fused to a PTD sequence. However, it does not provide for the ability of the protein to function as

claimed in an in vivo manner. The expression of a fusion protein in vitro does not confer in vivo success, and as such one of skill in the art would be forced to experiment to determine if the fusion of a enzyme to a PTD would work effectively.

Claim Rejections Maintained- 35 USC § 103

7. The rejection of claims 34-35, 37-38, and 47-48 rejected under 35 USC 103 (a) as being obvious over Schwarze *et al* in view of Ghodsi *et al* (1999 or 1998) is ***maintained*** for the reasons of record. Applicant argues that differences exist between the protein disclosed by Schwarze *et al* reference and the instant application, and that such differences would not obviate the instant invention. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons.

Applicant contends that the protein is different because of processing of the protein. However, the intended usage of the protein^{as} ~~is~~ encompassed by the claims does not breath any merits into the claims. The protein disclosed by Schwarze *et al* and that disclosed by the instant application are polypeptides fused to a PTD. There is no recitation or proviso language provided in the claims to lead one of ordinary skill in the art to believe that bacterially expressed protein fused to a PTD sequence is any different from that disclosed in the instant application. Furthermore, applicant argues that the denatured form of the protein is not functional while the non-denatured form is, hence distinguishing the Schwarze *et al* reference from the instant application. However, no recitation exists for a non-denatured form of the protein. Furthermore, whether the protein is expressed in situ or expressed in a bacterial expression system,

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the protein disclosed by Schwarze *et al* and the instant invention are the same, namely a β -galactosidase fused to a PTD sequence.

Conclusion

8. No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Chris PHZ

Christopher Yaen
Art Unit 1642
December 1, 2002

[Handwritten signature]
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